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EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/314,052	Applicant(s) OTT ET AL.	
	Examiner Manuel A. Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2010 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

1. Claims 1-81 are cancelled. Claims 82-87 are pending.
2. Claims 82-87 were first proposed for entry on February 9, 2005. Applicants' remarks of that date stated these claims were copied from 09/896,821 (now USP 6,976,489, hereafter "Mantell").

Related Applications/Litigation

3. This application is a continuation in part of 09/081,186, which issued as USP 6,068,609 on May 30, 2000.
4. The same inventive entity also was issued USP 5,411,474 on May 2, 1995. This patent was issued an *ex parte* reexamination certificate on October 5, 2010.
5. Both of these patents were subjects of an appeal to the CAFC, which issued a ruling on August 28, 2008 ("Lexion Medical, LLC v Northgate Technologies, Inc, Smith & Nephew, Inc., and Linvatec Corporation"). In that decision, the claims of USP 6,068,609 were held to be invalid for obviousness because this patent "simply modifies the invention described in the '474 patent via a simple and minor improvement: adding a recharge part that allows for the replenishment of water for extended use during laparoscopic surgeries." (See decision filed as part of an IDS on November 26, 2008.)
6. The CAFC remanded the case involving USP 5,411,474 back to the district court. The US District Court of the Northern District of Illinois Eastern Division issued a Memorandum Opinion on April 27, 2009 (see IDS filed July 8, 2009), which granted Lexion's motion for summary judgment for Northgate's infringement of Claim 11 of USP

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5,411,474. In applicant's response of December 17, 2009, applicants advise the examiner that the District Court decision is currently on appeal to the CAFC, and that "[i]t only involves infringement issues. Judgment is final with respect to invalidity issues because the earlier decision of the Federal Circuit affirmed the jury's finding on validity."

7. Applicants' response of December 17, 2009 also states:

Of import to the Interference is the fact that the '474 patent is prior art to the current application. The current continuation-in-part application claims priority to application serial number 09/081,186, which is the application that led to the United States Letters Patent Number 6,608,609 ('609). Certain claims of the '609 patent were previously at issue in the litigation, **but those claims were declared invalid**, and that decision was affirmed by the Court of Appeals for the Federal Circuit. Accordingly, the litigation has been concluded with respect to the '609 patent. Therefore, there is no ongoing litigation on issues concerning related subject matter, and the Examiner is courteously requested to expeditiously complete the setting of the Interference upon receipt of this Supplemental Amendment. [Emphasis added.]

8. Applicants filed a terminal disclaimer on May 17, 2006 and again on October 18, 2006 to overcome the examiner's double patenting rejections of the pending claims.

The terminal disclaimer was filed by Lexion Medical, LLC to disclaim the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent No. 6,068,609. This terminal disclaimer was approved on November 6, 2006. As the claims of USP 6,068,609 have been declared invalid for obviousness, the currently pending claims must also be held to be unpatentable for obviousness. Such a rejection will be made in this Office action.

9. Further, as applicants have acknowledged, USP 5,411,474 "is prior art to the current application." As the claims of 6,068,609 were held to be invalid over 5,411,474,

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that USP remains as prior art against the claims now pending. For purposes of this Office action, the Examiner has assumed the '474 patent was the reason the '609 claims were declared invalid for obviousness, rather than for inherency. Therefore, the examiner is modifying the grounds of rejection in order to be consistent with the apparent judgment at both the district court and appellate level.

Interference

10. The request for interference filed originally on February 9, 2005 is acknowledged. However, examination of this application has not been completed as required by 37 CFR 41.102(a). Consideration of a potential interference is premature. See MPEP § 2303.

11. Applicant has suggested an interference pursuant to 37 CFR 41.202(a) in a communication filed on October 25, 2007, on August 12, 2008 and on November 21, 2008.

Applicant failed to provide a detailed explanation as to why applicant will prevail on priority. See 37 CFR 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c).

Claims 82-87 has been added or amended in a communication filed on February 9, 2005 to provoke an interference. Applicant failed to provide a claim chart showing the written description for each claim in the applicant's specification. See 37 CFR 41.202(a)(5) and MPEP § 2304.02(d).

12. Applicants state that the present application claims the benefit of a filing date of May 18, 1999, but as that priority claim is for a continuation in part, applicants'

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statements fail to provide a detailed explanation as to why applicant will prevail on priority under 37 CFR 41.202(a)(4), (a)(6), (d).

13. On pages 16-19, applicants address the requirements under 37 CFR 41.202(a)(5). However, this analysis fails to comply with rule's requirement for a claim chart.

14. Applicants' are advised that 37 CFR 41.201 states that "[w]here there is more than one count, each count must describe a patentably distinct invention." In the applicants' suggestion under 41.202, there are four proposed counts. Therefore, applicants appear to be stating that the claims encompass four patentably distinct inventions. Count I is associated with Claim 83; Count II with Claim 84; Count III with Claim 86; and Count IV with Claim 87. Should applicants continue to maintain the existence of four patentably distinct inventions, then the examiner may issue a restriction requirement. For purposes of this Office action, the examiner has assumed only one patentably distinct invention is being claimed in Claims 82-87.

15. At the time that the claims are deemed to be allowable, applicants will be invited to file a new statement under 41.202. Applicants are requested to address whether Claims 82 and 85 should be considered to be part of any potential count(s).

Agilent Analysis

16. According to *Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366 (Fed. Cir. 2009, 91 USPQ2d 1161):

...where the PTO assesses the viability of an applicant's claims in the face of §102 or §103 challenges, the proper reference point for determining claim meaning is the host disclosure, just as in *ex parte* prosecution. By contrast, as in the instant case, where the PTO must assess whether both

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parties have a right to claim the same subject matter, the claim construction analysis properly occurs in the context of the specification from which the claims were copied. (USPQ pp. 1166-1167)

17. Therefore, in accordance with the *Agilent* standard, for the purpose of evaluating applicant's Claims 82-87 for art rejections under 102/103, the claim meaning has been determined in light of applicant's own disclosure. That is consistent with the court's holding in *Rowe v. Dror*, 112 F.3d 473, 42 USPQ2d 1550 (Fed. Cir. 1997), where the court evaluated Rowe's (the copier's) claims in light of Rowe's own disclosure for the meaning of any phrases at issue in the determination of novelty or non-obviousness.

18. If the question is one of whether applicant can challenge Mantell's priority of invention by copying Mantell's claims, then applicant's copied claims must be interpreted in light of Mantell's originating disclosure. So, when considering whether applicant's specification contains an adequate written description of any claim clauses at issue, those claim clauses must be viewed in the context of Mantell's disclosure.

This is consistent with the court's holding in *In re Spina*, 975 F.2d 854, 24 USPQ2d 1142 (Fed. Cir. 1992), where Spina's claims, copied from Barron's patent, were evaluated for adequate written description by viewing the claim in light of the Barron patent's disclosure.

19. Regarding the analysis under *Spina*, the examiner has viewed applicants' copied claims in light of Mantell's originating disclosure.

Drawings

20. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). On April 27, 2010, applicants submitted new drawings. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because they were not marked in accordance with 37 CFR 1.121(d). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

21. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, an apparatus without a heater must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Claims 82 and 86 recite an apparatus without a heater. Throughout applicants' specification, the device is defined as a heater/hydrator, but on page 7, for example, the device is described as needing "only" hydration or humidification elements. Therefore, there appears to be support for this configuration, but it is not shown as an alternative embodiment.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

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number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

22. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

23. Applicant's abstract contains legal phraseology and fails to reflect the currently claimed invention.

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24. The disclosure is objected to because of the following informalities: on page 12, line 10 and line 20, there are two typographical errors.

In the amendment filed July 30, 2001, an amendment to the specification was made, but that amendment should have been made to page 4, line 27, not to page 3.

Applicants' amendment filed on April 27, 2010 appears to involve deletion of lines 17-23 on page 7. Applicants are requested to review that amendment and either modify it or confirm that was applicants' intention.

Appropriate correction is required.

25. The attempt to incorporate subject matter into this application by reference to USP 5,411,474 on page 2, and to "various patent publications" on page 25 is ineffective because USP 5,411,474 contains a blanket incorporation by reference statement, which itself is ineffective (see, for example, Col. 11, line 39).

26. The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective.

Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

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Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

Claim Rejections - 35 USC § 112, 1st paragraph

27. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

28. Claims 82-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been made consistent with the *Agilent Technologies* analysis set forth above.

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29. Applicants have claimed the following invention:

Claim	Ott et al.	Mantell 6,976,489
82	A gas humidification apparatus comprising:	Figs. 1-17
	an inlet;	inlet port (12) or (212)
	a humidification device in fluid communication with said inlet,	Figure 4 or (201)
	said humidification device comprising:	
	a humidification material that readily absorbs moisture and readily releases moisture when exposed to a dry environment,	humidification material Fig. 4 (24), or Fig. 5 (224); materials of nylon, cotton or other fibers that readily absorbs and releases moisture when exposed to a dry environment (Col. 5, lines 22-32 and Col. 6, lines 1-2)
	wherein said humidification material is placed within a shell that is not made of a material that readily absorbs moisture and readily releases moisture when exposed to a dry environment and	shell (26) can be made of any suitable material, for example, metal or plastic (Col. 6, lines 60-61)
	has a configuration that generates turbulence in a gas as it passes over a surface of said shell; and	shell (26) interior has a surface area of irregular pattern or texture or structures (Col. 6, lines 12-23 and Fig. 2)
	an outlet in fluid communication with said humidification device.	gas outlet (28)

30. Applicants' disclosure lacks an adequate written description supporting the invention claimed by Mantell. Applicants' humidification material is described as "liquid-retaining material" with a pore size of the selected material chosen "according to a balance of liquid-retaining capabilities and low pressure drop considerations."

(Specification, page 8, lines 8-14) Other embodiments apparently lack any liquid-retaining layers (page 8, line 16). While applicants disclose a chamber (128) that can be assumed to be resistant to moisture absorption, that was not expressly disclosed. However, applicants' disclosure is entirely devoid of any discussion that the surface of chamber (128) has a configuration that generates turbulence as it passes over a surface of the shell.

31. Claim 83 contains limitations regarding "a heater housing" with that housing having "a plurality of openings." The humidification material must surround the heater. There is also a second humidification material. As shown in Figures 5 and 17 of Mantell, there is a plurality of openings (219) in the heater housing (217). Applicants' lack a heater housing, and are using a heating element (see Figure 3). As there is no housing, there can be no plurality of openings as disclosed and claimed by Mantell.

32. Claim 84 requires the humidification material to have a configuration "that generates turbulence for a gas that should pass over a surface of said humidification material." Mantell clearly shows a star shaped pattern in Figures 4, 5, 12, and 17. The material is described as having "a patterned or varying 15 degrees of a non-smooth surface" (Col. 5, lines 31-33), and with serrated sections rotated relative to one another

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until a phase difference is achieved (Col. 5, lines 45-55). Applicants' only apparent disclosure of a structure targeting flow characteristics is seen in applicants' Figure 4 (element 123). On page 13, fluted surfaces 123 are described as facilitation complete dispersion of gas "as it is supplied to the heater/hydrator 120." These surfaces are clearly not part of the humidification material, and are external to the chamber 128.

33. Claim 85 also requires the humidification material to have a configuration that generates turbulence, which is not in applicants' possession. Further the humidification device "envelopes said heater." Mantell shows in Figures 1-3 the configuration which supports this claim limitation. Heater 18 is enclosed in a heater housing 20, which is enveloped by humidification material 24. Applicants' have layers through which the gas flows (from left to right in applicants' Figure 2). While multiple heating elements 134 may be used (see discussion on page 8), the heater is described as being "wire" that is "between liquid-retaining layers." Additionally, "heating elements may be disposed within the chamber." Applicants' disclosure fails to support any interpretation that the humidification device "envelopes" the heater as is clearly the claimed invention of Mantell.

34. Claim 86 contains the limitation of "turbulence means," which has been defined in Mantell as involving the interior of the shell 26 or the shaping of the humidification material 24. Applicants' turbulence means is solely defined as fluted surfaces 124, and therefore, the intended turbulence means is different between the two disclosures.

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35. Claims 82-86 were copied into this application on February 9, 2005. As these claims contain new matter, the reduction to practice date for these claims is considered to be their filing date.

Claim Rejections - 35 USC § 112, 2nd paragraph

36. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

37. Claims 82-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

38. Claims 82-87 recite limitations for “readily absorbs,” “readily releases” and “dry environment.” Claim 84 recites the sensor measures temperature “in an indirect manner.” Claim 85 recites a limitation of “an integral humidification material” that is “unbundled” and the material is a “unitary structure.” Claim 87 recites a “non-ambient gas” is measured in an “indirect manner.” All of these limitations fail to define the boundaries of the claimed invention, and are considered to be terms of degree and are subjective. The applicants’ specification lacks some standard for measuring the degree or scope of these terms. In fact, regarding applicants’ humidity control, it appears that this is a passive system. No action is required, and only an alarm is sounded. Fluids may or may not be reintroduced into the housing when the gas exiting drops below a “predetermined or user programmable threshold.” (See page 4, line 17-18, and page 14.) One user may not define a dry environment consistently with another user, which makes this language inherently vague and indefinite.

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39. Claim 87 lacks antecedent basis for "said inlet" (last line).

40. Claim 86 recites "inlet means," "turbulence means" and "outlet means."

Applicants' written description fails to disclose corresponding structure or acts for these limitations. Applicants' humidification device has an inlet, but there is no turbulence means within the humidification apparatus. The outlet from the device permits the exhausting of the gas, but "expelling" implies an active structure within the humidification apparatus to expel the gas. Applicants' outlet means is passive, not active.

Claim Interpretation

41. In light of the rejections under 35 USC 112 made above, the examiner has made the following assumptions regarding the claimed invention for the purpose of making art rejections.

Figure 2 has been interpreted as having an inlet 124, humidification material 130-132, a heater 134, and an outlet 126. The temperature is sensed by 136 and humidity sensed by 138. For purposes of art rejections, the shell has been interpreted as being the walls of chamber 128. Turbulence is assumed to occur as the gas passes through each respective layer of 130-132. While there is no heater housing, per se, the heating element 134 is shown as coiled (Figure 4) and therefore has been interpreted as showing openings between the coils.

Claim Rejections - 35 USC § 102

42. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

43. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

44. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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45. Claims 82-87, as best understood, are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 (a) as obvious over Ott ET al. 5,411,474 (hereafter, Ott '474).

46. The examiner maintains the rejections as set forth in the previous Office action, mailed on July 19, 2010. Those grounds are incorporated by reference into this action.

In addition to those grounds of rejection, the examiner relies on Ott '474 patent for its disclosure that "a high efficiency humidification bed 28, which can comprise "a porous bed" of entrapped water (Col. 8, line 15) as the humidification material. The material for the bed is selected for its "water retention capabilities" (Col. 8, lines 24-25). Heater element 20 is "embedded" in the humidification bed 28 (Col. 8, lines 37-38).

Ott '474 does not describe the material used for membranes 30, 32 (see Col. 6 and Figure 2), nor their purpose. A membrane will inherently have a filtering effect. Therefore, these membranes have been considered to be filters. Ott ' 474, Background of the Invention (Col. 2, bottom to Col. 3, top) describes the use of filters in the prior art that is "typically hydrophilic." Therefore, it would have been obvious to make the membranes 30,32 of hydrophilic material because it would enhance the humidification of the gas passing therethrough. It is noted that Ott '474 describes element 25 as a "hydrophobic filter" that filters gas as it "enters chamber 7" (see Col. 8, lines 59-60). As shown in Figure 2, chamber 7 is shown upstream of filter 25, which is inconsistent with the concept that the element 25 is only filtering gas entering chamber 7. Therefore, it would have been obvious to one of ordinary skill in the art to locate filter 25 in the appropriate places within the chamber 6 to filter out impurities. This filter could be made

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from either a hydrophobic or hydrophilic material, since both were known to those skilled in the art, and would be selected based upon different gases and/or procedures. Depending on the material of these filters, they would impart a humidification effect on the gas being used and would readily absorb or release moisture.

Alternatively, the bed 28 can be made such that it performs both a humidification as well as a filtering function (see Col. 8, lines 10-36). For bed 28 to be useful as a filter, it would have to occupy most of the chamber 6, otherwise, some gas would pass through unfiltered. Therefore, the Ott '474 elements 30, 32 do not need to be present, and the humidification material absorbs, releases moisture and has turbulence generated due to the gas passing through the chamber and coming in contact with the humidification material.

47. Alternatively, Claims 82-87, as best understood, are obvious over Ott '474 in accordance with the judgment of invalidity during the proceedings in *Lexion Medical v. Northgate Technologies*. Applicants have conceded that Ott '474 is prior art to this application. Applicants' have claimed priority from USP 6,068,609. The claims of USP 6,068,609 have been held to be invalid for obviousness over Ott '474. Applicants' have not contested the double patenting rejection made in this application against USP 6,068,609. Therefore, Claims 82-87 are rejected as obvious over Ott '474 because they are not patentably distinct from the claims held to be invalid.

48. Claims 82-87, as best understood, are rejected under 35 U.S.C. 102(e) as being clearly anticipated by USP 6,976,489 (Mantell et al.).

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49. As stated above, Claims 82-87 were entered into this application on February 9, 2005. Therefore, that date is considered to be the earliest constructive effective filing date for applicants' claimed invention. Mantell has a constructive effective filing date of June 29, 2001. Therefore, Mantell remains as prior art against applicants' claims.

Response to Arguments

50. Applicant's arguments with respect to claims 82-87 have been considered but are moot in view of the new ground(s) of rejection.

51. Applicant's arguments filed January 17, 2011 have been fully considered but they are not persuasive.

52. Applicants' argue that Ott '474 fails to refer to elements 30 and 32 as a "humidification material." Rather, these structures are "optional gas permeable membranes." As now discussed above in the rejections, these membranes can be filters which would be known to have hydrophilic or hydrophobic characteristics depending on the applications for the device. The examiner has gone on to outline why these membranes are not required to still apply the reference to these claims.

Applicants appear to want to dismantle the rejection, but these arguments do not address whether the reference reads on the claimed invention. Even if the examiner concedes applicants' position that "the entire teaching of ('474) patent teaches against the Examiner's conclusion" regarding the performance of membranes 30, 32 (see argument, page 10), the applicants' have not addressed the performance of the humidification bed itself.

Applicants, on page 11, top, state the humidification material of Ott '474 is not shown to readily absorb or readily release moisture when exposed to a dry environment, rather "it only teaches a material that retains moisture when infused with water." Applicants' argument appears to contradict itself. The material is for humidification. The applicants state the material "retains moisture," which inherently means the material has absorbed the moisture, and if it is for the purpose of humidification, it inherently releases the moisture.

53. Based upon the examiner's interpretations of applicants' copied claims, the rejections made in the Office action should not be construed as raising any issues regarding the validity of any other U.S. patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM